(c) and (d) Yes Sir, a sub committee of the CPCSEA (Committee for the purpose of Control and Supervision of Experiments on Animals), which is a body under the Ministry of Social Justice and Empowerment, have examined 18 projects involving large animals, (non-rodents), of which 10 projects, including dog studies, have been approved.

(e) During the last 2 years, three Investigational New Drugs (IND) applications have been received by the office of the Drug Controller of India.

Norms for clinical trials of drugs

263. SHRI SANJAY NIRUPAM: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the proposal mooted by the R&D Sub-Committee of CII's National Committee on Drugs and Pharmaceuticals, seeking changes in norms for clinical trials of drugs in the country; if so, the details thereof;

(b) the salient features of existing norms of clinical trials; and

(c) whether Government propose to amend the existing norms, on the basis of suggestions so received; if so, by when?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) No such proposal has been received.

(b) At present clinical trials in the country are governed by the provisions contained in Schedule Y of the Drugs and Cosmetics Act and Rules thereunder. The level of clinical trials required to be carried out before a new drug is approved for manufacture/marketing depends to an extent on the status of that drug in other countries.

If it has been already approved for manufacture or marketing and adequate documentation regarding the clinical trials done in that connection is available, then only Phase III trials, as laid down in Schedule Y of the Drug and Cosmetics Rules is required.

If the drug has not been approved elsewhere, then trials are

generally required from a level previous to the phase of trial underway in other countries.

For new drug substances discovered in other countries, Phase I trials are not usually allowed to be initiated in India, unless Phase I data relating to human/clinical pharmacology is available, exemption in this regard is available in cases where the drug has a special relevance in this country in terms of public health.

New drug substances discovered in this country need to undertake clinical trials right from Phase I.

(c) To streamline the process of conducting clinical trials of drugs and their clearance Government have *inter alia* taken the following measures:—

(1) A committee of experts has been set up *vide* order dated 17.01.2001 which also spells out the modalities for processing applications relating to investigational new drugs.

(2) Guidelines relating to Good Clinical Practices (GCP) are also being finalised for early publication.

World Bank assisted Health Schemes for Maharashtra

264. SHRI SURYABHAN PATIL VAHADANE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether some World Bank aided health care projects have been launched in Maharashtra;

(b) if so, the details thereof;

(c) the funds allocations made for these projects during the last three years, year-wise; and

(d) what is the allocation made for these projects for the Adivasi districts in the State?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to